

REMARKS

The Applicants thank the Examiner for the thorough consideration given the present application. Claims 6-10 are pending. Claims 1-5 are canceled without prejudice to or disclaimer of the subject matter contained therein. Claims 6-10 are added, and claims 6 and 10 are independent. The Examiner is respectfully requested to reconsider the rejections in view of the amendments and remarks set forth herein.

Claim for Priority

It is gratefully acknowledged that the Examiner has recognized the Applicants' claim for foreign priority. In view of the fact that the Applicants' claim for foreign priority has been perfected, no additional action is required from the Applicants at this time.

Drawings

The Applicants have not received a Notice of Draftsperson's Patent Drawing Review Form PTO-948, indicating whether the formal drawings have been approved by the Official Draftsperson. Clarification in the next official communication is respectfully requested.

Acknowledgement of Information Disclosure Statement

The Examiner has acknowledged the Information Disclosure Statement filed on January 30, 2002. An initialed copy of the Form PTO-1449 has been returned by the Examiner. No further action is necessary at this time.

Specification Objection

The Examiner has objected to the specification because of several informalities. In order to overcome this objection, the specification is amended herein in order to correct the deficiencies pointed out by the Examiner. Reconsideration and withdrawal of this objection are respectfully requested.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 1-5 stand rejected under 35 U.S.C. §112, second paragraph as being indefinite. This rejection is respectfully traversed.

In order to overcome this rejection, claims 1-5 are canceled and new claims 6-10 are added to correct each of the deficiencies specifically pointed out by the Examiner. Applicants respectfully submit that the claims, as amended, particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection Under 35 U.S.C. §103(a)

Claims 1-4 stand rejected under 35 U.S.C. §103(a) as being unpatentable over WO 96/34633 in view of Ebert et al. (U.S. 5,626,866). Claim 5 stands rejected under 35 U.S.C. §103(a) as being unpatentable over DeCandia et al. (U.S. 6,174,399). These rejections are respectfully traversed.

Added Independent Claim 6

While not conceding the appropriateness of the Examiner's rejection, but merely to advance prosecution of the instant application, independent claim 6 is added herein to recite a combination of elements directed to a pressure-sensitive adhesive substrate section which is sealed in bags in order to protect against a loss of an active substance, said substrate section comprising a backing layer; a matrix connected to said backing layer, the matrix either being comprised entirely of a pressure sensitive adhesive material or provided with a pressure-sensitive adhesive layer on its application surface; and a carrier layer covering the pressure-sensitive application surface of said matrix, projecting at least partially beyond said matrix, and being divided by an incision, thus forming a detachment aid, wherein said carrier layer is configured with two carrier layer sections overlapping each other in a region where they are joined in order to increase storage stability of said substrate section by avoiding leakage of the pressure-sensitive adhesive material.

Added claim 6 specifies that the substrate section of the present invention comprises a matrix which is self-adhesive, because it is either entirely comprised of a pressure-sensitive adhesive or provided with a pressure-sensitive adhesive on its application surface. Thus, the surface of the substrate section being applied to a patient's skin is adhesive covered by a carrier layer. The carrier layer in turn is divided by an incision such that two carrier layer sections are formed which overlap each other. In such substrate sections, leakage of the pressure-sensitive adhesive from the matrix through the incision is avoided such that the

substrate sections of the present invention does not stick to the inside of the bags or pouches in which they are sealed.

In contradistinction to the present invention, WO 96/34633 and U.S. 5,626,866 concern the loss of active substance rather than the avoidance of leakage of pressure sensitive adhesive. In particular WO 96/34633 teaches a dressing set comprising a non-occlusive backing that has one adhesive side, a reservoir and a foil between reservoir and backing layer to prevent loss of volatile active substance through the backing layer. The reservoir comprises at least one pharmaceutically active compound, but is neither rendered pressure-sensitive nor made on the basis of a pressure-sensitive adhesive. To mount the dressing set to the patient's skin, the non-occlusive backing layer projects beyond the reservoir such that it forms an adhesive edge.

Since WO 96/34633 does not relate to patches comprising a pressure-sensitive adhesive matrix/reservoir, it neither addresses nor indicates the problem of pressure-sensitive adhesive leaking from the matrix/reservoir through the incision of the carrier layer, Therefore, WO 96/34633 could not have made the present Invention obvious to the skilled artisan, even if Figure 2 indicates the presence of overlapping peel-strip sections.

U.S. 5,626,866 concerns a method for making a transdermal drug delivery device for heat sensitive and volatile drugs. The method comprises the steps of providing first and second adhesive laminates each comprising a drug permeable adhesive layer having laminated to one surface an Impermeable backing layer. The drug, in gelled form, is

extruded on either one or both of the adhesive surfaces of the two adhesive laminates which are then laminated together. In the examples, it might be disclosed to seal the devices in pouches. However, U.S. 5,626,866 does not teach the formation of carrier layer sections which overlap each other, nor is the problem of leaking pressure-sensitive adhesive disclosed or suggested.

Therefore, the Applicants respectfully submit that the combined view of WO 96/34533 and U.S. 5,626,866 fail to make the present invention obvious to the skilled artisan at the time the invention was made, because these documents fail to disclose any information leading towards the problem of leaking pressure-sensitive adhesive, or even indicate that said leaking might be avoided upon providing a substrate section with overlapping carrier layer sections.

In view of the above amendments and arguments, independent claim 6, and claims 7-9 depending therefrom, are in condition for allowance

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) are respectfully requested.

Added Independent Claim 10

Independent claim 10 is added herein to recite combination of method for forming pressure-sensitive adhesive substrate sections comprising carrier layer sections, said carrier layer sections projecting beyond the substrate sections and forming a region of overlap, the method comprising the step of supplying said pressure-sensitive adhesive substrate sections

to the carrier layer section via a dispensing process, after the step of overlapping the carrier layer sections.

With respect to independent claim 10, the Applicants respectfully note that the process for forming the pressure-sensitive substrate sections of the present invention significantly differs from the process according to U.S. 6,174,399. According to the known process, an elastic base material (19) is first provided with a non-woven fabric (11). The resulting laminate is first provided with a first release paper (32), and then provided with a second release paper (33) such that the two release papers overlap each other. Thus, the overlap of the release papers is achieved at the end of the assembly process.

In contradistinction, according to the process of present invention as set forth in independent claim 10, the two carrier layer sections are first overlapped, and then the substrate sections are supplied to the carrier layer sections already overlapping.

Furthermore, the substrate sections are supplied to the overlapping carrier layer sections via a dispensing process, whereas assembly of the layers according to U.S. 6,174,399 takes place in a continuous process, and the laminate is cut after the assembly process into strips.

U.S. 6,174,399 fails to disclose overlapping of the carrier layer sections / release papers prior to supplying the pressure-sensitive substrate, and fails to teach or suggest a dispensing process. Therefore, U.S. 6,174,399 could not have rendered the process of the present invention obvious to the skilled artisan.

Applicants respectfully submit that this combination of method steps as set forth in independent claim 10 is not disclosed or made obvious by the prior art of record, including U.S. 6,174,399, for the reasons explained above.

Therefore, claim 10 is in condition for allowance. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) are respectfully requested.

CONCLUSION

Since the remaining patents cited by the Examiner have not been utilized to reject claims, but merely to show the state of the art, no comment need be made with respect thereto.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. It is believed that a full and complete response has been made to the outstanding Office Action, and that the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone Carl T. Thomsen (Reg. No. 50,786) at (703) 205-8000.

Application No. 09/980,211
Amendment dated August 21, 2003
Reply to Office Action of May 21, 2003

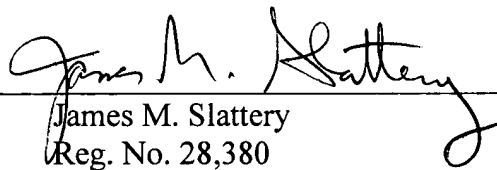
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If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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